

4 Post Office Square Road Acton, MA 01720 United States www.nqa-usa.com

COMPANY NAME: NASA Marshall Space Flight Center REPORT NUMBER: 06/AS-S07

AUDIT DATE(s): May 9-12, 2006

MAIN SITE ADDRESS	OTHER SITES VISITED				
Marshall Space Flight Center, AL 35812					
ISO 9001:2000: All Products and Services Provided by the Marshall S and is a Major Contributor to All Its Scientific and Technical Enterprise AS9100: Design, Development, Production, Installation and Servicing Equipment Interfacing with Flight Hardware and Fight Software.	ès.				
STANDARD APPLIED	ACTIVITY CATEGORY				
X ISO 9001 DOC REVIEW ISO 9001 w AS9100 PRE-ASSESSMENT ASSESSMENT	X SURVEILLANCE				
TEAM LEAD or LEAD AUDITOR	OTHER TEAM MEMBERS				
Rick Giguere, ANAB # A03158, AIEA					
ACTIVITY CONCLUSIO	NS: (check all that apply)				
X CONFORMING 2 NUMBER of OBSERVATIONS or OPPORTUNITIES FOR	1 NUMBER of MINORS RAISED IMPROVEMENT IDENTIFIED				
X REGISTRATION RECOMMENDED / CONTINUED REGISTRATION RECOMMENDED / CONTINUED REGISTRATION REQUIRED ON-SITE REVIEW OF CORRECTIVE ACTION REQUIRED	WORKING DAYS (from report date)				
NONCONFORMING WITH MAJOR NONCONFORMANCE REGISTRATION NOT RECOMMENDED					
SPECIAL VISIT REQUIRED	DURATION (audit days required)				
SPECIAL	COMMENTS				
Previously identified non-compliances have been satisfactorily at Non-compliances noted herein are minor in nature. The issue of record retention particularly as it relates to electronic					
△ ↓LEAD AUDITOR	COMPANY REPRESENTATIVE				
Rich Sug Z	Chales B. Chilwood				
within, has been reviewed and accepted.	indicates that this report, and any nonconformities and observations noted				
 Any nonconformities or observations identified are the result of a lin The Internal Audit system is deemed effective unless noted otherwi This report remains under established confidentiality agreements be Prior to the initial assessment, the organization must have per management review. The quality management system must be 	se within this report. etween NQA and the assessed organization. formed a full system internal audit, followed by a documented				



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AS9100 ASSESSMENT MATRIX AND PLANNER

] LECEND	r	T .	1			
ည	LEGEND	 	L				⊨
AS9100 REQUIREMENTS	X = Element Fully Assessed	MANAGEMENT ACTIVITIES	RESOURCE	PRODUCT REALIZATION PLANNING	PRODUCT REALIZATION	DESIGN & DEVELOPMENT	REASSESSMENT ACTIVITY
8 불	P = Partial Element Assessed		88	SEX	SΕ	88	ĭĕŢ
온표	E = Exclusions Taken	#F		5 88	검정	<u> </u>	88.≥
AS9100 UIREME	* = Audit each Activity	ANAGEMEN ACTIVITIES	SS	PRODUCT EALIZATIO PLANNING	PRODUCT	DESIGN &	SSESSM
Ö		A A	RESOURCE	모집되	표절	5 %	AS A
22		Σ	Σ.	🗠	œ	👸	. Ä
404	DOOLINENTATION OFFICE				· · · · · · · · · · · · · · · · · · ·		
4.2.1	DOCUMENTATION GENERAL	X	36	P		Р	X
4.2.2	QUALITY MANUAL*	X	X /	X	Х	Х	X
	CONTROL OF DOCUMENTS	P		Р	P	Р	Х
4.2.4	CONTROL OF RECORDS	Х		Р	P	Р	X
	CONFIGURATION MANAGEMENT	X					Х
5.1 5.2	MANAGEMENT COMMITMENT	X					Х
5.2	CUSTOMER FOCUS	X		P	<u> </u>	Р	. Х
5.4.1	QUALITY POLICY QUALITY OBJECTIVES*	Χ					Χ
5.4.2	- Water	X	X	Х	X ·	Х	X
5.5.1	QMS PLANNING RESPONSIBILITY & AUTHORITY	X					X
5.5.1	MANAGEMENT REPRESENTATIVE	X					Х
5.5.2		X	Р	Р	<u> </u>	Р	Х
5.6	INTERNAL COMMUNICATION MANAGEMENT REVIEW*	Х		Р	Р	Р	Х
6.1	PROVISION OF RESOURCES	X	X	Х	Х	Х	Х
6.2.1	HUMAN RESOURCES GENERAL	Р	X				X
6.2.2	COMPETENCE, AWARENESS & TRAINING		Х				X
6.3	INFRASTRUCTURE		X	P		Р	Х
6.4	WORK ENVIRONMENT		X	Р	P		X
7.1	PLANNING PRODUCT REALIZATION		Х	Р	Р		X X X
7.2.1	DETERMINATION OF REQUIREMENTS			Х			X
7.2.1				Х			X
7.2.2	REVIEW OF PRODUCT REQUIREMENTS CUSTOMER COMMUNICATION			Х			Х
7.3	DESIGN & DEVELOPMENT			Х	·		Х
7.4.1	PURCHASING PROCESS					X	X X X
7.4.1	PURCHASING PROCESS PURCHASING INFORMATION	-		X			X
7.4.2	VERIFICATION OF PURCHASED PRODUCT			X			X
7.4.3	CONTROL OF PROVISION			X	Р		X
7.5.1	VALIDATION OF PROCESSES				Х		X
7.5.3	IDENTIFICATION & TRACEABILITY				X		X
7.5.4	CUSTOMER PROPERTY	-			X		X
7.5.4	PRESERVATION OF PRODUCT				X		X
7.5.5	MONITORING & MEASUREMENT DEVICES				X		X
8.1	MEASUREMENT, ANALYSIS & IMPROVEMENT				X		X ·
8.2.1	CUSTOMER SATISFACTION*	X				- V	X
8.2.2	INTERNAL AUDIT*		X	X	X	X	Х
8.2.3	PROCESS MONITORING/MEASUREMENT	X	Х	Х	X	Х	X
8.2.4	PRODUCT MONITORING/MEASUREMENT	X P			P		X
8.3	CONTROL NONCONFORMING PRODUCT	P			X		X
8.4	ANALYSIS OF DATA*	. X		P	X	V.	X
8.5.1	CONTINUAL IMPROVEMENT*		X	X	X	X.	. X
8.5.2	CORRECTIVE ACTION*	X	X	X	X	X	X
8.5.3	PREVENTIVE ACTION*	X	X	X	X	X	X
0.0.3	USE OF MARKS*	X	X	X	X	X	X
	USE OF WARRS		Х	Х	Х	Χ	X

CURRENT SECTIONS COVERED (S	URVEILLANCE NUMBER)	AS-S07			
FUTURE SURVEILLANCE	NEXT VISITS		AS-S08	AS-S08	
PLANNING	FOLLOWING YEAR		·		AS-S09



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AUDIT ACTIVITY RECORD

Audit trail reviewed / Personnel interviewed / Documentation reviewed / Departments or Processes Audited
Objective evidence sampled

Reference also AS9101B checklist for further details

(5.5, 5.6, 5.4.1, 8.2.1, 8.5.1, 8.4)

Reviewed IMSB Activity as per 1280.1, dated April 18, 2006. Interviewed R. Henderson/DE01. Verified adequacy of review inputs and outputs.

Reviewed PMC Meeting minutes dated 4/20/06. Interviewed R. Gladwin/CS10.

Interviewed C. Seabrook/DA01, regarding customer satisfaction indicators for Programs and Projects as per MPR 1280.8.

(8.1, 8.2.3, 8.2.4, 8.3, 8.5.2, 4.2.3, 4.2.4, 4.3)

SSME: Interviewed R. Patrick regarding assessment activities performed by QD20 in support of Shuttle Project Office, as per QD-PA-001 and processing failure investigations, Mishap reports as per QD-PA-002. (1 Obs)

CLV Flight Software: Interviewed T. Brown, B. Truss, EV22, El32. Reviewed Peer review process on MPLC Project, per E132-OI-001, software Review Board activity and processing SCRR's. Also reviewed audit activity and related nonconformity processing in the SA SCR tracking System.

NASA STARS: Interviewed D. Jeffreys, D. Stanley, HS20. Discussed Workforce planning, Staffing and OPM metrics. Reviewed method for processing position announcements, including position descriptions, vacancy Notices, postings and approvals, use of job descriptions, skills identification and use of STARS database. Also reviewed and discussed associated records, including retention periods and disposition of records as per OPM Appendix C.

Shuttle NEQA: Reference MP-OWI-15 and MWI-5330.2. Interviewed S. Davis/MP. Reviewed process for planning and conducting NEQA evaluations at contractors (ATK). Observed recent audit dated 4/24-25/06 and discussed processing identified nonconformities and related corrective actions, reporting results and verification and closure of actions. (1 NC / 1 Obs) Space Act Agreement Process: Interviewed J. Seemann, L. Durnya, LS01. Reference NPD 1050.1 and LS-OI-01. Sampled SAAM # 987, Reviewed and discussed performance measures related to objectives.

Protective Services: Reviewed and discussed protective services related to people, information and assets as per AD50-OWI-001, Surveillance Process for Security Services Contract, including Metrics as per MADR. Reviewed Quarterly Report Summary for most recent quarter ending 2/28/06 and metrics related to objectives. Also reviewed and discussed improvement activities as evidenced in Kaizen events, preventive activities and customer satisfaction indicators.

Spacecraft and Vehicle Dept.: Interviewed E. Adams/EV61. Reviewed process for evaluating contractor performance, sampled Task order 22-010203 and CAITS # 6-8121-0002, 06-EI21-0004, 06-EI21-0003.

8.2.2, 4.2.3, 4.2.4, 8.5.2

Internal audit as per MPR 1280.6, Interviewed Kerry Warner/QD40.

8.5.1, 8.5.2, 8.5.3, 4.2.4

Corrective Action and Preventive action. Interviewed J. McPherson/HEI. Reference MPR1280.4 Interviewed L. Creel/EI31, Appreciative Inquiry Team Lead for Lessons Learned. Reviewed and discussed improvement initiative within Instrument & Payload Systems. Reviewed 5 focus areas.

AREAS OF GOOD PERFORMANCE

SLV Flight Software personnel with command of requirements and records at fingertips.

Protective services use of Kaizen events for improvement. Listening to voice of customer and initiating change in response.

AREAS FOR IMPROVEMENT

Appreciative Inquiry improvement initiative should make use of trained six sigma black belts to facilitate improvements. More defined approach on how to disposition electronic records at the end of their required life.



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NONCONFORMANCES AND OBSERVATIONS

NUM	REF	ISSUES RAISED	CLASS
1	4.2.3	REQUIREMENT STATED: QD-PA-001, Records section 8.2 & 8.3, and QD-PA-002, Records section 8.5 ISSUE RAISED: The above noted sections include incorrect references to QD10 and QD20.	OBS
2	8.2.3	REQUIREMENT STATED: MWI 5330.2, NASA Engineering & Quality Audit, states that "A preliminary report shall be given at the exit briefing with a final report 30 days after the briefing." Also: "the team chairperson shall sign final verification of completed corrective action along with the project manager." ISSUE RAISED: Final reports are provided once per year at Summit, and final verification of corrective action is signed by Marshall field office personnel.	NC
3	8.2.3	REQUIREMENT STATED: MWI 5330.2 NEQA, Cause determination ISSUE RAISED: A review of corrective actions related to NEQA audit findings reveals that the form used to document corrective actions does facilitate recording cause determinations which ensures a more effective corrective action. Appendix Z of this document does have an extensive list of cause codes, but they are not noted on the form.	OBS
. 4		REQUIREMENT STATED: ISSUE RAISED:	-
5	·	REQUIREMENT STATED: ISSUE RAISED:	
6		REQUIREMENT STATED: ISSUE RAISED:	
7		REQUIREMENT STATED: ISSUE RAISED:	

·	ASSESSMENT SCORING			(Mem	ber logo)		
Organiz	ation : NASA, Marshall Space Flight Ctr.			Res	sult		
	SCORING CHART		R or minor on Key ement	Minor CA Key requ	R on <u>non</u> uirement	NO CAR	RESULT
		Multiple findings	Single finding	Multiple findings	Single finding	,	
4	Quality management system					(100)	100
4.1	General requirements	0	10	25	. 40	50	50
4.2 & 4.3	Documentation requirements & Configuration management	0	10	25	40	50	50
- 5	Management responsibility					(150)	150
5.1	Management commitment						
5.2	Customer focus	0	5	15	20	30	30
5.3	Quality policy		3	15	20	30	·
5.4	Planning	0	10	20	30	40	40
5.5	Responsibility, authority and communication	0	5	15	20	30	30
5.6	Management review	0	10	25	40	50	50
6	Resource Management					(100)	100
6.1	Provision of resources	0	40	75	40	FO	
6.2	Human resources	1 "	10	25	40	50	50
6.3	Infrastructure	0	10	25	40	50	
6.4	Work environment	1	10	25	40	50	50
7	Product realization					(450)	
7.1	Planning of product realization	0	5	15	20	30	30
7.2	Customer related processes	0	10	30	50	60	60
7.3	Design and development		1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		L-parameter -		
7.3.1	D& D Planning	0	5	15	20	30	30
7.3.2-3-4	Inputs, outputs & review	0	5	15	20	30	30
7.3.5-6	D&D verification & validation	0	5	15	20	30	30
7.3.7	Control of design and development changes	0	5	15	20	30	30
7.4	Purchasing	0	10	30	50	60	60
7.5	Product and service provision	la de la					
7.5.1		0	10	25	40	50	50
7.5.2	Validation of processes for production and service provision	0	10	20	30	40	40
7.5.3	Identification and traceability	0	10	20	30	40	40
7.5.4-5	Customer property & preservation of product	0	5	15	20	30	30
7.6	Control of monitoring and measuring device	0	5	10	15	20	20
8	Measurement analysis and improvement					(200)	200
8.1	General	0	5	10	15	20	20
8.2	Monitoring and measurement	W				1	
8.2.1	Customer satisfaction	0	5	10	15	20	20
	Internal audit	0	5	15	20	30	30
	Monitoring and measurement of processes	0	5	15	20	30	20
	Monitoring and measurement of product	0	5	15	20	30	30
8.3	Control of nonconforming product	0	5	15	20	30	30
8.4	Analysis of Data	0	5	10	15	20	20
8.5	Improvement	0	5	10	15	20	20
	•			-	TOTAL	880 ⁽¹⁾ or 1000	990
The assess	sed Organization agrees on the Quality System scoring and C	orrective Ac	tion		SCORE	99/	100

Charles Chitwood

Signature:

1206

ASSESSMENT REPORT

Assessing company logo

	·					
ASSESSMENT CONCLUSIONS						
General comments about the organization a	and the quality system of the assessed organization:					
1. Good overall consistency of management s						
	•					
·						
•	,					
Strong points:						
1. El-32 CLV Flight Software, Baraka Truss,	in command of requirements and records.					
2. Improvements to hazardous chemicals ar	nd age sensitive materials.					
3. Kaizen events in Protective Services						
•						
Improvement Opportunities:						

- 1. Control of electronic records at end of life
- 2. Make use of existing skills regarding improvement initiatives, i.e. black belts.

ASSESSMENT REPORT

Assessing company logo

GENERAL ASSESSMENT INFORMATION							
1 Organization & Work Addr	ess		,				
Company Name: NASA, Marsh	nall Space Flight Ce	enter	Tel Number: 256-544-0	451			
			Fax Number: 256-544-4	1155			
Subsidiary of:			e-mail: robin.henderson	ı@msfc.nasa			
Organization Identification:			CAGE code:				
Assessed Site Address: Hunts	ville, AL 35812		Assessment Representative & Title: Robin Henderson, Associate Director Quality Manager Representative & Title: Robin Henderson, Associate Director				
Main activities:							
Product Types or Codes:	Wheate						
2 ISO Registration							
[] ISO Registered			Registrar Name: NC	QA-USA			
[x] ISO Standard / Revision Is			Expiration Date (If applicable):				
[x] Aerospace Standard / Rev	vision AS9100B		May 27, 2007				
3 Assessment Team	***************************************		1				
Lead Assessor Name: Rick G	iguere		Other Assessor Team Members:				
[x] Certified Auditor – Type &	No. A03158						
[] Qualified Auditor							
4 Assessment Dates: May 9	-12, 2006						
5 Assessment Scope							
[] Total facility assessed	[] Initial assessr	nent	[] All 9100 elements as	ssessed			
[x] Partial facility assessed	[]Re-assessme	ent	[x] Partial 9100 elements assessed				
[] Other:			Elements not assessed:				
[] Activity assessed:							
6 Assessment Disposition			7 Scoring				
[] Conforming			Scoring result: 99				
[x]Conforming with minor (mi) corrective action		·				
[] Non conforming with Major	(MA) corrective act	ion					
8 Assessment Approval							
Assessing Company	Date	L	ead Assessor Name	Signature			
NQA-USA	May 12, 2006		Richard Giguere	met fly			

Distribution Agreement

This Assessment Report is the property of the assessed Organization and the assessing Company. Distribution to other companies or individuals is authorized only after written agreement of the assessed Organization and of the assessing Company.

To that end, a signature below by an Authorized Representative of the assessing company indicates that the copied by the organization for other customers.	is report may be
If copied, the report must be disclosed in full including findings and any corrective actions.	
Authorized Representative Assessing Company NameRichard Giguere Signature	ate 5/12/01
	-

ASSESSMENT REPORT

Assessing company logo

ASSESSMENT RESULT SUMMARY

Elements*		Res	sult		Observation / Corrective Action Request Number
(AS9100 – Section 1)					
4 - Quality Management System					
4.1 General requirements	S				
4.2 Documentation requirements	S				1 Observation
4.3 Configuration Management	S				
5 - Management responsibility					
5.1 Management commitment	S				
5.2 Customer focus	S				
5.3 Quality policy	S				
5.4 Planning	s	<u> </u>			
5.5 Responsibility, authority and communication	S				
5.6 Management review	S			1	
6 - Resource managements		·			
6.1 Provision of resources	S				
6.2 Human resources	S				
6.3 Infrastructure	S				
6.4 Work environment	S				
7 - Product realization					
7.1 Planning of product realization	S				
7.2 Customer-related processes	S				
7.3 Design and development	S				
7.4 Purchasing	S				
7.5 Production and service provision	S				
7.6 Control of monitoring and measuring devices	S				
8 - Measurement, analysis and im	orove	ment			
8.1 General	S				
8.2 Monitoring and measurement			1		1 Observation
8.3 Control of NC product	S				:
8.4 Analysis of data	S				
8.5 Improvement	S				
Assessed Organization: NASA, Marshall Space Flight Ctr.)		1		Assessing Company: N Q A, USA
Rep's name: Signature: Changes Changes		Res	ults		Lead Assessor Name: Richard Giguere Signature:

^{*} For each element, cross results of assessment: "S" for Satisfactory, "Ma" for major corrective action, "mi" for minor or "N/A" for nor applicable

APPENDIX A AS9101

QUALITY SYSTEM QUESTIONNAIRE

	QUALITY SYSTEM QUESTIONNAIRE					
	ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
4	QUALITY MANAGEMENT SYSTEM					
4.1	General requirements					
ma	is the organization established, documented, implemented and maintained a quality anagement system and continually improve its effectiveness in accordance with the quirements of this International Standard?	77117	/			
02 Do a) b) c) d) e)	throughout the organization (1)? determine the sequence and interaction of these processes (1)? determine criteria and methods needed to ensure that both the operation and control of these processes are effective? ensure the availability of resources and information necessary to support the operation and monitoring of these processes? monitor, measure and analyze these processes? and implement actions necessary to achieve planned results and continual improvement of these		\ 			
	processes ? e these processes managed by the organization in accordance with the requirements of this ernational Standard ?		7			
04 Wr	nere an organization chooses to outsource any process that affects product conformity with quirements, does the organization ensure control over such processes?	P	U			
05 lst	the control of such outsource processes identified within the quality management system?		1			
produc Suid a	Processes needed for the quality management system referred to above should include put realization and measurement. ance Note	processes to	ir ma	nagement,	provis	ion,
	n process formally identified e.g. : list, flow diagram, etc.	-				
Objec	tive evidence assessed / Observations / Comments / N/A explanation					
	See detail within					
		·				

	QUALITY SYSTEM QUESTIONNAIRE							
	ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E		
4.2	Documentation requirements							
4.2.1	General							
a) b) c) d) e) f)	documented statements of a quality policy and quality objectives? a quality manual? documented procedures required by this International Standard? documents needed by the organization to ensure the effective planning, operation and control of its processes? records required by this International Standard (see 4.2.4)? and quality system requirements imposed by the applicable Regulatory Authorities? es the organization ensure that personnel have access to quality management system commentation and are aware of relevant procedures?		\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \					
08 Do Customer and/or regulatory authority representatives have access to quality management system documentation?			1					
4.2.2	Quality manual MPD 1280.1 Resof		<u> </u>		January 1	1		
09 Ha: a) b)	the scope of the quality management system, including details of, and justification for, any exclusions? the documented procedures established for the quality management system, or reference to them, and when referencing the documented procedures, is the relationship between the requirements of this International Standard and the documented procedures clearly shown (2)? a description of the interaction between the processes of the quality management system?		/					
Note 1	: Where the term "documented procedure" appears within this International Standard, this me	ans that the	e proc	edure is es	tablisl	hed.		

Note 1: Where the term "documented procedure" appears within this International Standard, this means that the procedure is established, documented, implemented and maintained.

Note 2: The extent of the quality management system documentation can differ from one organization to another due to

Objective evidence assessed / Observations / Comments / N/A explanation

- a) the size of organization and type of activities,
- b) the complexity of processes and their interactions, and
- c) the competence of personnel

Guidance Notes

- 1) Quality manual reference and issue
- 2) Check the procedure list

Documented system remains fully documented regularly reviewed

Manual current, sensitive and responsible to glagulatory requirement.

Reviewed Manual for changes

QUALITY SYSTEM QUESTIONNAIRE					
ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma.or.mi	N/A	N/E
Documentation requirements (continued)		•			
Control of documents	1				
e the documents required by the quality management system controlled ?	M				
e records controlled according to the requirements given in 4.2.4?					
s a documented procedure been established to define the controls needed to: approve documents for adequacy prior to issue? review and update as necessary and re-approve documents? ensure that changes and the current revision status of documents are identified? ensure that relevant versions of applicable documents are available at points of use? ensure that documents remain legible and readily identifiable? ensure that documents of external origin are identified and their distribution controlled? and prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose?			Õss		
es the organization coordinate document changes with customers and/or regulatory thorities in accordance with contract or regulatory requirements?					
Control of records	[{************************************			[
e records established and maintained to provide evidence of conformity to requirements and the effective operation of the quality management system?	**************************************	/			
records remain legible, readily identifiable and retrievable (1) ?		/			
s a documented procedure been established to define the controls needed for the ntification, storage, protection, retrieval, retention time and disposition of records?		/			
es the documented procedure define the method for controlling records that are ated by and/or retained by suppliers?		J			
e records available for review by customers and regulatory authorities in accordance th contract or regulatory requirements ?	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	/			
Configuration management					
s the organization established, documented and maintained a configuration management cess appropriate to the product?	P				/
ance Note records reviewed					
ive evidence assessed / Observations / Comments / N/A explanation					
423 not seview of in ontirety. Reviewed seconds et various function of level See notes Resein.					
	Documentation requirements (continued) Control of documents a the documents required by the quality management system controlled? a records controlled according to the requirements given in 4.2.4? a documented procedure been established to define the controls needed to: approve documents for adequacy prior to issue? review and update as necessary and re-approve documents are identified? ensure that changes and the current revision status of documents are identified? ensure that couments remain legible and readily identifiable? ensure that documents of external origin are identified and their distribution controlled? and prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose? as the organization coordinate document changes with customers and/or regulatory thorities in accordance with contract or regulatory requirements? Control of records records established and maintained to provide evidence of conformity to requirements and the effective operation of the quality management system? records remain legible, readily identifiable and retrievable (1)? a documented procedure been established to define the controls needed for the ntification, storage, protection, retrieval, retention time and disposition of records? By the documented procedure define the method for controlling records that are ated by and/or retained by suppliers? Configuration management the organization established, documented and maintained a configuration management cases appropriate to the product? Configuration management the organization established, documented and maintained a configuration management cases appropriate to the product? Configuration management the organization established, documented and maintained a configuration management cases appropriate to the product?	Documentation requirements (continued) Control of documents as the documents required by the quality management system controlled? If the control of documents as the documents required by the quality management system controlled? If the control of documents required by the quality management system controlled? If the control of documents are decording to the requirements given in 4.2.4? If the documents required by the quality management system controls needed to: approve documents for adequacy prior to issue? review and update as necessary and re-approve documents? review and update as necessary and re-approve documents are identified? ensure that documents remain legible and readily identifiable? ensure that documents of external origin are identified and their distribution controlled? and prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose? If the organization coordinate document changes with customers and/or regulatory fubrities in accordance with contract or regulatory requirements? Control of records The effective operation of the quality management system? Records established and maintained to provide evidence of conformity to requirements and the effective operation of the quality management system? Records remain legible, readily identifiable and retrievable (1)? If a documented procedure been established to define the controls needed for the antification, storage, protection, retrieval, retention time and disposition of records? If the organization established, documented and maintained a configuration management are the organization established, documented and maintained a configuration management are the organization established, documented and maintained a configuration management are records reviewed If the organization established, documented and maintained a configuration management are provided by suppliers? Configuration management assessed / Observations / Comments / N/A explanation Advanced to the	Documentation requirements (continued) Control of documents a the documents required by the quality management system controlled? a the documents required by the quality management system controlled? a the documents required by the quality management system controlled? a the documents are documents of adequacy prior to issue? a records controlled according to the requirements given in 4.2.4.? a a documented procedure been established to define the controls needed to: approve documents for adequacy prior to issue? review and update as necessary and re-approve documents ? resource that changes and the current revision status of documents are identified? ensure that changes and the current revision status of documents are identified? ensure that documents remain legible and readily identifiable? ensure that documents remain legible and readily identifiable? ensure that documents remain legible and readily identifiable? ensure that documents of external origin are identified and their distribution controlled? and prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose? The state organization coordinate document changes with customers and/or regulatory requirements? Control of records The records established and maintained to provide evidence of conformity to requirements and the effective operation of the quality management system? The records established and maintained to provide evidence of conformity to requirements and the effective operation of the quality management system? The records remain legible, readily identifiable and retrievable (1)? The state of procedure define the method for controlling records that are attend by and/or retained by suppliers? The records available for review by customers and regulatory authorities in accordance in the contract or regulatory requirements? Configuration management The organization established, documented and maintained a configuration management of the organization est	ASSESSMENT QUESTIONS Requirements S	ASSESSMENT QUESTIONS Requirements S CAR NV.

S MANAGEMENT RESPONSIBILITY 5.1 Management commitment 01 Has Top management provided evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by (1): a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements? b) establishing the quality policy? c) ensuring that quality policy? c) ensuring that quality of resources? 5.2 Customer focus 02 Has Top management ensured that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1)? 5.3 Quality policy 03 Has Top management ensured that the quality policy: a) is appropriate to the purpose of the organization? b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system? c) provides a framework for establishing and reviewing quality objectives? d) is communicated and understood within the organization (2)? and e) is reviewed for continuing suitability? 5.4.1 Quality objectives 04 Has Top management ensured that quality objectives, including those needed to meet requirements for product (see 7.1 a)] are established at relevant functions and levels within the organization (3)? 05 Are the quality objectives 06 Has Top management ensured that: a) the planning of the quality management system is carried out in order to meet the requirements (see 4.1), as well as the quality objectives and b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented? Guidance Notes 1) Evidence of management commitment 2) Identify and records method of communication 3) Review objectives and status of their implementation Objective evidence assessed / Observations / Comments / N/A explanation Apachus - (2) is 3 grays. Cympur yearston, Roles is 4.	QUALITY SYSTEM QUESTIONNAIRE								
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Objectivs - (7) in 3 groups (Superin execution, Roles in Sy									
related Hetries		* *							
Reviewed Policy and discussion related to continued appropria	listenen,								

S: Satisfactory - CAR: Corrective action required - Ma: Major corrective action - mi: Minor corrective action N/A: Not applicable - N/E: Not evaluated - P: Product - M: Management

QUALITY SYSTEM QUESTIONNAIRE			-		
ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number	N/A	N/E
	1		Ma or mi		
5.5 Responsibility, authority and communication	-				
5.5.1 Responsibility and authority	1		1		<u> </u>
07 Has Top management ensured that the responsibilities and authorities are defined and communicated within the organization (1)?		V		111111111111111111111111111111111111111	
5.5.2 Management representative		<u> </u>			
08 Has Top management appointed a member of management who, irrespective of other responsibilities, has responsibility and authority that includes: a) ensuring that processes needed for the quality management system are established, implemented and maintained? b) reporting to top management on the performance of the quality management system and any need for improvement? c) ensuring the promotion of awareness of customer requirements throughout the organization	M .	1			
? and					
d) the organizational freedom to resolve matters pertaining to quality? 5.5.3 Internal communication	<u> </u>	<u> </u>		<u></u>	
O9 Has Top management ensured that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system?	1	J	·		
Guidance Note					
Identify and records method of communication within the organization					
Objective evidence assessed / Observations / Comments / N/A explanation					
Objective evidence assessed / Observations / Comments / N/A explanation Pel. Pro My Mintes 4/24/24 Open Action Status Status of Action Regicus Action Language Action Lan	tourieu	of 10	ich Gla	dun	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~
57 45 - Mouls Status					***************************************
States of Action Reojects					nindensonami por agenga
Action Lans closed					***************************************
MWATTE Constitut - Reformance C	refored				***************************************
Molestones-					
- Factities Utilization Commitment					***************************************

	ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/
5.6	Management review					
5.6.1	General					
	as Top management reviewed the organization's quality management system, at planned tervals, to ensure its continuing suitability, adequacy and effectiveness (1)?					
	nes this review include assessing opportunities for improvement and the need for changes to equality management system, including the quality policy and quality objectives?					
12 Ar	e records from management reviews maintained (see 4.2.4) ?		1			
5.6.2	Review input NPR 1280, 1		•			
13 Dc	es the input to management review include information on (2):	<u>M</u>			ļ ₁	
a)	results of audits?					
b)	customer feedback?					
c)	process performance and product conformity?					
d)	status of preventive and corrective actions?					
e)	follow-up actions from previous management reviews?					
f)	changes that could affect the quality management system? And					
g)	recommendations for improvement?					
5.6.3	Review output					
14 Do	es the output from the management review include any decisions and actions related to (2):	<u>M</u>		,		
d)	improvement of the effectiveness of the quality management system and its processes?		:/			
e)	improvement of product related to customer requirements? And		עי			
		18 8 1	, 11		13 E	B

Objective evidence assessed / Observations / Comments / N/A explanation

2) Verify the availability of input / output data such as: statistical data; graphics; summary tables; reports; etc.

1) Records management review frequency and functions involved (e.g : quality, production, etc.)

IMSB Bi Annual Management System Rev. Apr. 18, 2006

Action From - follow-up

· Objectives - defined

· Cust. Sat - independent Survey.

· Proc. Paf./Pend. Cef. (PMC activity / Directions Oranin

Jul Anolit - data NCS

Con. Act. bu Act - Metries, Sheet, GIDEP

Japanent. Walface Planing + Dev.

Infrastructure Myst. Centre Opo Proces

QUALITY SYSTEM QUESTIONNAIRE								
ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A N/E				
6. RESOURCE MANAGEMENT								
6.1 Provision of resources								
D1 Has the organization determined and provided the resources needed: a) to implement and maintain the quality management system and continually improve its effectiveness? And b) to enhance customer satisfaction by meeting customer requirements?								
6.2 Human resources	<u> </u>							
6.2.1 General								
02 Are personnel performing work affecting product quality competent on the basis of appropriate education, training, skills and experience (1)?								
6.2.2 Competence, awareness and training								
 03 Does the organization: a) determine the necessary competence for personnel performing work affecting product quality (2)? b) provide training or take other actions to satisfy these needs? c) Evaluate the effectiveness of the actions taken? d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives? e) maintain appropriate records of education, training, skills and experience (see 4.2.4) (3)? 	P		·	V				
6.3 Infrastructure	<u> </u>		<u></u>					
Out Does the organization determine, provide and maintain the infrastructure needed to achieve conformity to product requirements? Infrastructure includes, as applicable: a) buildings, workspace and associated utilities? b) process equipment (both hardware and software)? And c) supporting services (such as transport or communication)?				V				
6.4 Work environment				/				
05 Does the organization determine and manage the work environment needed to achieve conformity to product requirements?	P							
$\underline{\text{Note}}$: Factors that may affect the conformity of the product include temperature, humidity, lighting, cl discharge, etc.	eanliness, pr	otectio	on from elec	trostatic				
Guidance Notes 1) Review training Records and Plan (status of the current year and of the previous year) 2) Give examples of methods used to determine competence (e.g.: competence matrix, multiskill,) 3) Review training certificates for the certified personnel and training records (internal and external training certificates)	ining course	s)						
Objective evidence assessed / Observations / Comments / N/A explanation								

QUALITY SYSTEM QUESTIONNAIRE			* #.		
ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E

7. PRODUCT REALIZATION

7.1		Planning of product realization			,			
01	Does (see	the organization plan and develop the processes needed for product realization? 4.1)		:	***************************************			
02	•	anning of product realization consistent with the requirements of the other processes of the ty management system (see 4.1)?						
03	In pla a)	nning product realization, does the organization determine the following, as appropriate : quality objectives and requirements for the product?			:			
	b)	the need to establish processes, documents, and provide resources specific to the product?						
	c)	required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance?			***************************************	ACTION AC		
	d)	records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4) ?	F		**************************************			
	e)	the identification of resources to support operation and maintenance of the product?						/
04	s the o	output of this planning in a form suitable for the organization's method of operations?						

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QUALITY SYSTEM QUESTIONNAIRE								
ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E			
7.2 Customer-related processes								
7.2.1 Determination of requirements related to the product								
Does the organization determine: a) requirements specified by the customer, including the requirements for delivery and post-delivery activities? b) requirements not stated by the customer but necessary for specified or intended use, where known?	M							
c) statutory and regulatory requirements related to the product? andd) any additional requirements determined by the organization?								
d) any additional requirements determined by the organization? 7.2.2 Review of requirements related to the product		<u></u>	<u> </u>	111	<u> </u>			
•								
Of Does the organization review the requirements related to the product? Of Is the review conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of	P							
changes to contracts or orders) and does it ensure that (1): a) product requirements are defined? b) contract or order requirements differing from those previously expressed are resolved? c) the organization has the ability to meet the defined requirements? And d) risks (e.g., new technology, short delivery time scale) have been evaluated?	en de la companya de				***************************************			
08 Are records of the results of the review and actions arising from the review maintained (see 4.2.4) (2)?								
09 Where the customer provides no documented statement of requirement, are the customer requirements confirmed by the organization before acceptance?		***************************************	1					
10 Where product requirements are changed, does the organization ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements?	P							
Note: In some situations, such as internet sales, a formal review is impractical for each order. Insproduct information such as catalogues or advertising material.	tead the rev	iew ca	an cover th	e rele	vant			
7.2.3 Customer communication								
 Does the organization determine and implement effective arrangements for communicating with customers in relation to: a) product information? b) enquiries, contracts or order handling, including amendments? and c) customer feedback, including customer complaints? 				-	/			
Guidance Notes								
Check that all affected functions are involved in the review Give examples				-				
Objective evidence assessed / Observations / Comments / N/A explanation					•			

			·		TARRESTANDA CONTRACTOR AND			

QUALITY SYSTEM QUESTIONNAIRE

	ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number	N/A	N/E
				Ma or mi		L
7.3	Design and development					
7.3.1	Design and development planning		•			
12 D	oes the organization plan and control the design and development of product?					N
13 Dı	uring the design and development planning, does the organization determine:	М			***************************************	
a)	the design and development stages (1) ?					H
	 in respect of organization, task sequence, mandatory steps, significant stages and method of configuration control, 					
b)	the review, verification and validation that are appropriate to each design and development					
	stage ? and					
c)	the responsibilities and authorities for design and development?					
14 V	here appropriate, due to complexity, does the organization give consideration to the					П
fo	ollowing activities :					
	- structuring the design effort into significant elements ?					
	 for each element, analyzing the tasks and the necessary resources for its design and development. Does This analysis consider an identified responsible person, 					
	design content, input data, planning constraints, and performance conditions. Is					
	the input data specific to each element reviewed to ensure consistency with					
	requirements ?					
	oes the organization manage the interfaces between different groups involved in design and evelopment to ensure effective communication and clear assignment of responsibility?					
16 ls	planning output updated, as appropriate, as the design and development progresses ?					
17 Ar	e the different design and development tasks to be carried out defined according to	Р		-		17
	pecified safety or functional objectives of the product in accordance with customer					V
	nd/or regulatory authority requirements (2) ?					
7.3.2	Design and development inputs					
	re inputs relating to product requirements determined and are records maintained (see 4.2.4)	M	··········		ļı	
•	3) ?					
	o these inputs include : functional and performance requirements ?					1
	applicable statutory and regulatory requirements ?					
-	where applicable, information derived from previous similar designs ? and					
d)	other requirements essential for design and development?					
19 Aı	re these inputs reviewed for adequacy?					17
20 A	re requirements completed, unambiguous and not in conflict with each other?					7
	N					
	ance Notes					
	ve at least an example of a completed design & development plan, or an example of one in p sks and key events.	rogress, tna	it ider	itifies the pi	annın	g of
2) Gi	ve an example				•	
3) Re	eview applicable input data (give examples)					
Objec	tive evidence assessed / Observations / Comments / N/A explanation					
		······································		·····	••••••	

QUALITY SYSTEM QUESTIONNAIRE										
		ASSESSMENT QUESTIONS	KEY Requirements	s	CAR Number Ma or mi	N/A	N/E			
_7	3	Design and development (continued)	•							
7.	3.3	Design and development outputs								
21	Ar	e the outputs of design and development provided in a form that enables verification against					,			
	the	e design and development input and approved prior to release?								
22	Do	the design and development outputs :	М			-				
	a)	, , , , , , , , , , , , , , , , , , , ,					\Box			
1	b)	provide appropriate information for purchasing, production and for service provision?				200				
	c)	contain or reference product acceptance criteria ?				- Control Control				
	d)	specify the characteristics of the product that are essential for its safe and proper use? and								
	e)	identify key characteristics, when applicable, in accordance with design or contract requirements?								
23		ll pertinent data required to allow the product to be identified, manufactured,	M				T			
	insp	ected, used and maintained defined by the organization; for example:								
		- drawings, part lists, specifications ?								
	,	- a listing of those drawings, part lists, and specifications necessary to define the configuration and the design features of the product?								
		- information on material, processes, type of manufacturing and assembly of the								
<u> </u>		product necessary to ensure the conformity of the product ?					4-4			
	3.4	Design and development review		r			\perp			
24		suitable stages, are systematic reviews of design and development performed in accordance	M				4-1			
	witr a)	planned arrangements (see 7.3.1) to (1): evaluate the ability of the results of Design and development to meet requirements?								
	b)	identify any problems and propose necessary actions? and								
	•	authorize progression to the next stage?								
25		participants in such reviews include representatives of functions concerned with the design					+			
``		development stage(s) being reviewed?								
		records of the results of the reviews and any necessary actions maintained (see 4.2.4)?					+			
7.3		Design and development verification					+			
				1			+			
2.1		arification performed in accordance with planned arrangements (see 7.3.1) to ensure that design and development outputs have met the design and development input requirements?					1/			
28		, , , , , , , , , , , , , , , , , , , ,		-			+			
20	AIC.	records of the results of the reviews and any necessary actions maintained (see 4.2.4)?					<u> </u>			
<u>No</u>	<u>te</u> : - - -	Design and/or development verification may include activities such as: performing alternative calculations comparing the new design with a similar proven design, if available undertaking tests and demonstrations, and reviewing the design stage documents before release.								
		To the standard and standard an								
		ance Notes								
1)	G	ve evidence of reviews								
Ob	ject	ive evidence assessed / Observations / Comments / N/A explanation								

QUALITY SYSTEM QUESTIONNAIRE	KEY S	CAR	N/A N/E
ASSESSMENT QUESTIONS	Requirements	Number Ma or mi	
7.3 Design and development (continued)			
7.3.6 Design and development validation	÷		
29 Is design and development validation performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known?	P		
30 Wherever practicable, is validation completed prior to the delivery or implementation of the Product?	777		
31 Are records of the results of validation and any necessary actions maintained (see 4.2.4) ?			
Note: - Design and/or development validation follows successful design and/or development verification. - Validation is normally performed under operating conditions. - Validation is normally performed on the final product, but may be necessary in the earlier stages product and the final product in	orior to product com	pletion.	-
7.3.6.1 Documentation of design and/or development verification and validation			
32 At the completion of design and/or development, does the organization ensure that reports, calculations, test results, etc., demonstrate that the product definition meets the specification requirements for all identified operational conditions?	M		
7.3.6.2 Design and/or development verification and validation testing	1_ 1		
 33 Where tests are necessary for verification and validation, are these tests planned, controlled, reviewed, and documented to ensure and prove the following (1): a) test plans or specifications identify the product being tested and the resources being used, define test objectives and conditions, parameters to be recorded, and relevant acceptance criteria? b) test procedures describe the method of operation, the performance of the test, and the recording of the results? c) the correct configuration standard of the product is submitted for the test? d) the requirements of the test plan and the test procedures are observed? e) the acceptance criteria are met? 	t		
Guidance Note	· · · · · · · · · · · · · · · · · · ·		
Give an example of a qualification report			
Objective evidence assessed / Observations / Comments / N/A explanation			
Objective evidence assessed / Observations / Comments / N/A explanation			
	·		
			:

QUALITY SYSTEM QUESTIONNAIRE								
ASSESSMENT QUESTIONS	KEY Requirements	s	CAR Number Ma or mi	N/A	N/E			
7.3 Design and development (continued)								
7.3.7 Control of design and development changes		I						
34 Are design and development changes identified and records maintained ?					1			
35 Are the changes reviewed, verified and validated, as appropriate, and approved before implementation (1) ?	P		·					
36 Does the review of design and development changes include evaluation of the effect of the changes on constituent parts and product already delivered ?	P							
37 Does the organization's change control process provide for customer and/or regulatory authority approval of changes, when required by contract or regulatory requirement?					Ц,			
38 Records of the results of the review of changes and any necessary actions maintained .(see 4.2.4)?					<u></u>			
Guidance Note								
1) Give an example								
Objective evidence assessed / Observations / Comments / N/A explanation								
	•							
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	QUALITY SYSTEM QUESTIONNAIRE	KEY	s	CAR	N/A	N/E
	ASSESSMENT QUESTIONS	Requirements		Number Ma or mi	17	,
7.4	Purchasing					
7.4	1 Purchasing process					
39	Does the organization ensure that purchased product conforms to specified purchase Requirements?	P	,			
40	Is the type and extent of control applied to the Supplier and the purchased product dependent upon the effect of the purchased product on subsequent product realization or the final product?					
	Is the organization responsible for the quality of all products purchased from suppliers, including customer-designated sources ?					
	Does the organization evaluate and select Suppliers based on their ability to supply product in accordance with the organization's requirements?					
	Are criteria for selection, evaluation and re-evaluation established ?					
	Are records of the results of evaluations and any necessary actions arising from the evaluation maintained (see 4.2.4) ?					4
45	Does the organization : a) Maintain a register of approved Suppliers that includes the scope of the approval (1) ?	M				
	 Periodically review Suppliers performance and use the records of these reviews as a basis for establishing the level of controls to be implemented (2)? Define the necessary actions to take when dealing with Suppliers that do not meet 		311143744444444444444444444444444444444			
	requirements ? d) Ensure where required that both the organization and all Suppliers use customer-approved special process sources ?		To the state of th			· ·
	e) Ensure that the function having responsibility for approving Supplier quality systems has the authority to disapprove the use of sources?					
Gı	idance Notes					
	Review current list of approved Suppliers Review suppliers performance / measurement system (e.g.: supplier rating, etc.)					
Obj	ective evidence assessed / Observations / Comments / N/A explanation					
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		;				
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QUALITY SYSTEM QUESTIONNAIRE

N/A N/E

ASSESSMENT QUESTIONS Requireme Number Ma or mi 7.4 Purchasing (continued) 7.4.2 **Purchasing information** 46 Does purchasing information describe the product to be purchased, including where appropriate (1): requirements for approval of product, procedures, processes and equipment? requirements for qualification of personnel? quality management system requirements? the name or other positive identification, and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical requirements for design, test, examination, inspection and related instructions for acceptance by the Organization? requirements for test specimens (e.g., production method, number, storage conditions) for design approval, inspection, investigation or auditing? requirements relative to : - supplier notification to Organizationr of nonconforming product? and - arrangements for Organizationr approval of supplier nonconforming material? requirements for the supplier to notify the Organization of changes in product and/or process definition and, where required, obtain organization approval? right of access by the organization, their customer, and authorities to all facilities involved in the order and to all applicable records? and requirements for the supplier to flow down to subtier suppliers the applicable requirements in the purchasing documents, including key characteristics where 47 Does the organization ensure the adequacy of specified purchase requirements prior to their communication to the supplier? **Guidance Note** 1) Examine purchase orders that apply to several types of procurement. Objective evidence assessed / Observations / Comments / N/A explanation

	QUALITY SYSTEM QUESTIONNAIRE					
	ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	·N/A	N/E
7.	4 Purchasing (continued)					
7.4	3.3 Verification of purchased product				* *	
48	Does the organization establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements, they may include obtaining objective evidence of the quality of the product from suppliers (e.g., accompanying documentation, certificate of conformity, test reports, statistical records, process control, inspection and audit at supplier's premises, review of the required documentation, inspection of products upon receipt, and, delegation of verification to the supplier, or supplier certification?	Р			-	
49	Is purchased product held until it has been verified as conforming to specified requirements unless it is released under positive recall procedure?					
50	Where the organization utilizes test reports to verify purchased product, is the data in those reports acceptable per applicable specifications (1)?					
51	Does the organization periodically validate test reports for raw material (1) ?					
52	Where the organization delegates verification activities to the supplier, are the requirements for delegation defined and a register of delegations maintained (1) ?					
53	Where the organization or its customer intends to perform verification at the supplier's premises, does the organization state the intended verification arrangements and method of product release in the purchasing information?					
54	Where specified in the contract, is the customer or the customer's representative afforded the right to verify at the supplier's premises and the organization's premises that subcontracted product conforms to specified requirements?					
55	It is ensured that verification by the customer is not used by the organization as evidence of effective control of quality by the supplier (it does not absolve the organization of the responsibility to provide acceptable product, nor shall it preclude subsequent rejection by the customer)?					1
Gι	ildance Note			-		
1)	Give an example					
Obj	ective evidence assessed / Observations / Comments / N/A explanation					
			***************************************	**************************************		

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	ASSESSMENT QUESTIONS	KEY	S	CAR	N/A	П
	ASSESSMENT QUESTIONS	Requirements	<u> </u>	Number Ma or mi		
7.5	Production and service provision					
7.5.1	Control of production and service provision					_
56 Does	planning consider, as applicable :					Г
	- the establishment of process controls and development of control plans where key characteristics have been identified					*
	- the identification of in-process verification points when adequate verification of conformance cannot be performed at a later stage of realization	P				١
	- the design, manufacture, and use of tooling so that variable measurements can be taken, particularly for key characteristics, and					
	- special processes (see 7.5.2).					L
	s the organization plan and carry out production and service provision under controlled litions (1).					
Do t	nese controlled conditions include, as applicable :	-				
a)	the availability of information that describes the characteristics of the product?					
b)	the availability of work instructions, as necessary?					
c)	the use of suitable equipment?					
d)	the availability and use of monitoring and measuring devices?					
e)	the implementation of monitoring and measurement?					
f)	the implementation of release, delivery and post-delivery activities?					
g)	accountability for all product during manufacture (e.g., parts quantities, split orders, nonconforming product)?					
h)	evidence that all manufacturing and inspection operations have been completed as planned, or as otherwise documented and authorized?	Р	***************************************			-
i)	provision for the prevention, detection, and removal of foreign objects?	P	***************************************			-
j)	monitoring and control of utilities and supplies such as water, compressed air, electricity and chemical products to the extent they affect product quality? and					***************************************
	authoria for condemanable, which shall be attached in the alcount areatical account	1 1				1
	auléaula fau recolousamable, rebiale aball ba aélarelatad la tha alaareat arratiaal maaraar					1
	criteria for workmanship, which shall be stipulated in the clearest practical manner (e.g., written standards, representative samples or illustrations)? nce Notes he Part Number(s) used for this review					
Guida	(e.g., written standards, representative samples or illustrations)? nce Notes he Part Number(s) used for this review					_
Guida	(e.g., written standards, representative samples or illustrations) ? nce Notes					
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	QUALITY SYSTEM QUESTIONNAIRE					
	ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
7.5	Production and service provision (continued)					
7.5.1.1	Production documentation					
58 Are	production operations carried out in accordance with approved data?					
59 Doe	s the data contain as necessary :	P			,	
a) b)	drawings, parts lists, process flow charts including inspection operations, production documents (e.g., manufacturing plans, traveler, router, work order, process cards); and inspection documents (see 8.2.4.1)? and a list of specific or non-specific tools and numerical control (NC) machine programs		***************************************			
	required and any specific instructions associated with their use ?	·	į			
7.5.1.2		L		i	11	-
-		M	=			╬
and	the organization identified and obtained acceptance of changes that require customer Nor regulatory authority approval in accordance with contract or regulatory uirements?			•		
	changes affecting processes, production equipment, tools and programs cumented ?	Р				
63 Are	procedures available to control their implementation ?					
	the results of changes to production processes assessed to confirm that the desired ect has been achieved without adverse effects to product quality ?	Р				
7.5.1.3	Control of production equipment, tools and numerical control (N.C.) machine program	I was a second	<u> </u>		 	
ins	production equipment, tools and programs validated prior to use and maintained and pected periodically according to documented procedures?					Ц
the	design data/specification ?	Р				
for	storage requirements, including periodic preservation/condition checks, established production equipment or tooling in storage?					Ц_
7.5.1.4	Control of work transferred, on a temporary basis, outside the organization's facilities	1			1	+
fac	en planning to temporarily transfer work to a location outside the organization's ilities, does the organization define the process to control and validate the quality of work?	M				<u> </u>
Guida	ance Notes					
1) Clea	arly defined list or procedures					
Object	ive evidence assessed / Observations / Comments / N/A explanation					

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<u> </u>	-					

	one new total and the second of the second o					
	QUALITY SYSTEM QUESTIONNAIRE	·····				
	ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/
7.5	Production and service provision (continued)					
7.5.1.5	Control of service operations					
69 Wh	ere servicing is a specified requirement, do service operation processes provide for :					Ē
a)	a method of collecting and analyzing in-service data?					,
ь)	actions to be taken where problems are identified after delivery, including investigation, reporting activities, and actions on service information consistent with contractual and/or regulatory requirements (1) (2)?			***************************************		l
c)	the control and updating of technical documentation?					
d) e)	the approval, control, and use of repair schemes (3) ? and, the controls required for off-site work (e.g., organization's work undertaken at the		•			
	customer's facilities) ?					L
7.5.2	Validation of processes for production and service provision					
70 Doe	s the organization validate any processes for production and service provision where the	Р			-	_
	ulting output cannot be verified by subsequent monitoring or measurement (This includes					
_	processes where deficiencies become apparent only after the product is in use or the					
Note:	vice has been delivered) (4)? These processes are frequently referred to as special processes.					
	es validation demonstrate the ability of these processes to achieve planned results?					Ħ
	the organization established arrangements for these processes including, as applicable :	M		<u>k</u>		T
a)	defined criteria for review and approval of the processes ?	-				Π
•	-qualification and approval of special processes prior to use ?					1
b)	approval of equipment and qualification of personnel ?					V
c)	use of specific methods and procedures ?					- The continue
·	- control of the significant operations and parameters of special processes in accordance with documented process specifications and changes thereto (5) ?					
d)	requirements for records (see 4.2.4) ?					
e)	and revalidation?					
0:-	N-4				[h	
	nce Notes iew reports issued following visits to the customer (technical support). Comment on method of	f callaction a	f in a	oniae dete	Even	ine
som	e investigation reports	Conection	11 11 50	ei vice data.	Exam	IIIIE
	iew evidence of implementation of corrective and preventive actions. iew evidence of what has been assessed (e.g.: maintenance manual, repair manual, informati	on to custon	nėr)			
Veri	fy the existence of list of special processes.	On to caston	icij			
5) GIVE	examples					
Object	ve evidence assessed / Observations / Comments / N/A explanation					
					•••••••••••••••••••••••••••••••••••••••	*****
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	QUALITY SYSTE	M QUESTIONNAIRE					
	ASSESSMENT QUESTIONS		KEY Requirements	s	CAR Number Ma or mi	N/A	N/E
7.5 Production and	service provision (continu	ed)					
7.5.3 Identification and	traceability						
73 Where appropriate, has the product realization?	ne organization identified the produ	ct by suitable means throughout					1
	naintain the identification of the d lifferences between the actual		P				
75 Has the organization iden requirements?	tified the product status with respect	t to monitoring and measurement		,			
	nority media are used (e.g., s ganization establish and documen						
77 Where traceability is a identification of the product	requirement, does the organization (see 4.2.4) ?	n control and record the unique					
	traceability required by contract, i ganization's system provide for (2		Р	,	£		
b) all the products mar	naintained throughout the product oufactured from the same batch of in to be traced, as well as the des e batch?	f raw material or from the same			THE PROPERTY OF THE PROPERTY O		
assembly to be trace	t, a sequential record of its produ						
Note: In some industry sectors	s, configuration management is a me	eans by which identification and tra	ceability is m	nainta	ined.		
7.5.4 Customer property							
	rcise care with customer property w	hile it is under the organization's					
	fied, verified, protected and safegua	arded customer property provided					
81 Does the organization def	ine methods to identify and record le unusable and report such to the c						V
Note: Customer property can inspection.	include intellectual property, include	ding customer furnished data	used for de	sign,	productio	n and	d/or
Guidance Notes 1) Give examples of method(s 2) Give examples of traceabili 3) Identify types of product su	ty level applied (up and down)			-			
Objective evidence asse	essed / Observations / Com	ments / N/A explanation					
•							
				·······			

	QUALITY SYSTEM QUESTIONNAIRE					
	ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	WE
7.5	Production and service provision (continued)					
7.5.5	Preservation of product					
	s the organization preserve the conformity of product during internal processing and delivery be intended destination?					
33 Does	the preservation include identification, handling, packaging, storage and protection?					
4 Does	preservation also apply to the constituent parts of a product ?					
spe	s preservation of product also include, where applicable in accordance with product cifications and/or regulations, provisions for :	Р	-			\prod
a)	cleaning?					
b)	prevention, detection and removal of foreign objects?					
c)	special handling for sensitive products ?					
d)	marking and labeling including safety warnings ?					
e) f)	shelf life control and stock rotation ? special handling for hazardous materials ?			January C		
	es the organization ensure that documents required by the contract/order to					+,
acco	ompany the product are present at delivery and are protected against loss and prioration?					V
Objecti	ve evidence assessed / Observations / Comments / N/A explanation		•			
			************	······································	······································	***************************************
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		QUALITY SYSTEM QUESTIONNAIRE					
		ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	NE
7	6	Control of monitoring and measuring devices					
	moni	es the organization determine the monitoring and measurement to be undertaken and the toring and measuring devices needed to provide evidence of conformity of product to mined requirements (see 7.2.1) (1)?	Р				Ī
88	an uni	es the organization maintain a register of these monitoring and measuring devices, define the process employed for their calibration including details of equipment type, que identification, location, frequency of checks, check method and acceptance teria?	M		Terrorian		
so: als	twar o inc	Monitoring and measuring devices include, but are not limited to: test hardware, test e, automated test equipment (ATE) and plotters used to produce inspection data. It cludes personally owned and customer supplied equipment used to provide evidence act conformity.			A THE REAL PROPERTY OF THE PRO		
89	car	es the organization establish processes to ensure that monitoring and measurement can be ried out and are carried out in a manner that is consistent with the monitoring and asurement requirements?					
90	Do cal	es the organization ensure that environmental conditions are suitable for the ibrations, inspections, measurements and tests being carried out?					
91		ere necessary to ensure valid results, is measuring equipment:					Ħ
	a)	calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded (2)?	THE PARTY OF THE P				
	b)	adjusted or re-adjusted as necessary?	- Table 1				
	c)	identified to enable the calibration status to be determined?					•
	d)	safeguarded from adjustments that would invalidate the measurement result?					
	e) <i>f)</i>	protected from damage and deterioration during handling, maintenance and storage? <u>recalled to a defined method when requiring calibration?</u>					
92	Doe equ	s the organization assess and record the validity of the previous measuring results when the ipment is found not to conform to requirements?					
93	Does	s the organization take appropriate action on the equipment and any product affected?	P				
94	Are	records of the results of calibration and verification maintained (see 4.2.4)?					Ħ
95	Whe	en used in the monitoring and measurement of specified requirements, is the ability of uputer software to satisfy the intended application confirmed?	Р				1,
96	Is th	s undertaken prior to initial use and reconfirmed as necessary?					7
G	ıida	nce Notes	· · ·				
1)	Rev Anal	iew that the organization has a process for ensuring the capability of measurement systeysis, Gage Repeatable & Reproducibility, etc.)	m (e.g. Inte	erval .	Analysis, R	esolut	ion
2)		ure the links to the recognized international / national standard.					
Ωh	iecti	ive evidence assessed / Observations / Comments / N/A evaluation					

Objective evidence assessed	/ Observations / Comme	nts / N/A explanation	
	•		
		•	

QUALITY SYSTEM QUESTIONNAIRE

8.1 General 10 Does the organization plan and implement the monitoring, measurement, analysis and improvement processes needed (1): a) to demonstrate conformity of the product? b) to ensure conformity of the quality management system, and? c) to continually improve the effectiveness of the quality management system? 20 Does this include determination of applicable methods, including statistical techniques, and the extent of their use? Note: According to the nature of the product and depending on the specified requirements, statistical techniques may be used to support: design verification (e.g., reliability, maintainability, safety); process control: escletton and inspection of key characteristics; solection and inspection of key characteristics; inspection—matching sampling rate to the criticality of the product and to the process capability: inspection—matching sampling rate to the criticality of the product and to the process capability; inspection—matching sampling rate to the criticality of the product and to the process capability; inspection—matching sampling rate to the criticality of the product and to the process capability; inspection—matching sampling rate to the criticality of the product and to the process capability; inspection—matching sampling rate to the criticality of the product and to the process capability; inspection—matching sampling rate to the criticality of the product and to the process capability; inspection—matching sampling rate to the criticality of the product and to the process capability; inspection—matching sampling rate to the criticality of the product and to the process capability; inspection—matching sampling rate to the criticality of the product and to the process capability; inspection—matching sampling rate to the criticality of the product and to the process capability; inspection—matching sampling rate to the crit	ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
Of Does the organization plan and implement the monitoring, measurement, analysis and improvement processes needed (1): a) to demonstrate conformity of the product? b) to ensure conformity of the product so the quality management system, and? c) to continually improve the effectiveness of the quality management system? Of Does this include determination of applicable methods, including statistical techniques, and the extent of their use? Note: According to the nature of the product and depending on the specified requirements, statistical techniques may be used to support: design verification (e.g., reliability, maintainability, safety); process control: selection and inspection of key characteristics; process control; statistical process control; design of experiment; inspection matching sampling rate to the criticality of the product and to the process capability; failure mode and effect analysis. Guidance Notes (1) Give examples of data Objective evidence assessed / Observations / Comments / N/A explanation If of Thur June Serman — Attorney— Authority Test facilities - agreement with instrusted fauture NPD 1050, 16 LS-0I-01 Rur 12 Ind. Rur. Chifamul On Rembussh Igan Let Agreemet — 5:Aan 4787	8 MEASUREMENT, ANALYSIS AND IMPROVEMENT					
improvement processes needed (1): a) to demonstrate conformity of the product? b) to ensure conformity of the quality management system, and? c) to continually improve the effectiveness of the quality management system? 20 Does this include determination of applicable methods, including statistical techniques, and the extent of their use? Note: According to the nature of the product and depending on the specified requirements, statistical techniques may be used to support: design verification (e.g., reliability, maintainability, safety); process control: selection and inspection of key characteristics; process control: statistical process control; design of experiment; inspection - matching sampling rate to the criticality of the product and to the process capability; failure mode and effect analysis. Guidance Notes Give examples of data Disjective evidence assessed / Observations / Comments / N/A explanation If of Thur Jean Art Agreement - Attorney - Jean Art Agreeme	8.1 General					
a) to demonstrate conformity of the product? b) to ensure conformity of the quality management system, and? c) to continually improve the effectiveness of the quality management system? 102 Does this include determination of applicable methods, including statistical techniques, and the extent of their use? 103 Does this include determination of applicable methods, including statistical techniques, and the extent of their use? 104 Does this include determination of applicable methods, including statistical techniques, and the extent of their use? 105 Does this include determination of applicable methods, including statistical techniques, and the extent of their use? 106 Does this include determination of applicable methods, including statistical techniques, and the extent of their use? 106 Description of the product and depending on the specified requirements, statistical techniques may be used to support the extent of the product and to the specified requirements, statistical techniques may be used to support the extension of the extensio	01 Does the organization plan and implement the monitoring, measurement, analysis	and M			ļ	
b) to ensure conformity of the quality management system, and? c) to continually improve the effectiveness of the quality management system? 102 Does this include determination of applicable methods, including statistical techniques, and the extent of their use? 103 Mote: According to the nature of the product and depending on the specified requirements, statistical techniques may be used to support: - design verification (e.g., reliability, maintainability, safety); - process control: - selection and inspection of key characteristics; - process capability measurements; - inspection - matching sampling rate to the criticality of the product and to the process capability; - failure mode and effect analysis. 103 Give examples of data 104 Dejective evidence assessed / Observations / Comments / N/A explanation 116 June Add Agreement - while in the criticality of the product and to the process capability; - agreement with intensed fauture 116 June Add Agreement - while in the continual of the process capability; - agreement with intensed fauture 117 June Add Agreement - while intensed fauture 118 June Add Agreement - while intensed fauture 118 June Add Agreement - Attensed fauture 118 June Remain - Attensed fauture 118 June Rema		ASSERTICES .				
c) to continually improve the effectiveness of the quality management system? 102 Does this include determination of applicable methods, including statistical techniques, and the extent of their use? 103 Mote: According to the nature of the product and depending on the specified requirements, statistical techniques may be used to support: 104 design verification (e.g., reliability, maintainability, safety); 105 process control: 105 eselection and inspection of key characteristics; 105 process capability measurements; 105 statistical process control; 105 eselection and inspection of key characteristics; 105 process capability measurements; 105 eselection and inspection of key characteristics; 106 eselign of experiment; 107 eselection — matching sampling rate to the criticality of the product and to the process capability; 107 failure mode and effect analysis. 108 Guidance Notes 109 Give examples of data 109 Dipoctive evidence assessed / Observations / Comments / N/A explanation 1177 Fund 1		-	1			
Does this include determination of applicable methods, including statistical techniques, and the extent of their use? Note: According to the nature of the product and depending on the specified requirements, statistical techniques may be used to support: - design verification (e.g., reliability, maintainability, safety); - process control: - selection and inspection of key characteristics; - process capability measurements; - statistical process control; - design of experiment; - inspection – matching sampling rate to the criticality of the product and to the process capability; - failure mode and effect analysis. Guidance Notes 1) Give examples of data Disjective evidence assessed / Observations / Comments / N/A explanation Ipart Turn Jerus Act Agreement — whilying Test facilities - agreement and instrusted facilities NPD 1050, 1 G LS-0I-01 Rur 12 Sant Rus, Chifloursal Non-Reimbrusch Jaan Act Agreement — 5.4Am # 987			\mathcal{V}			
Note: According to the nature of the product and depending on the specified requirements, statistical techniques may be used to support: - design verification (e.g., reliability, maintainability, safety); - process control: • selection and inspection of key characteristics; • process capability measurements; • statistical process control; • design of experiment; • inspection – matching sampling rate to the criticality of the product and to the process capability; • failure mode and effect analysis. Guidance Notes 1) Give examples of data Disjective evidence assessed / Observations / Comments / N/A explanation I profit for Serman – Attorney – Lyna Act Agreement with instrusted parties NPD 1050, 1 G LS - O I - Ol Rur 12 Sord Rur. Chifcanal O Non-Reinbursch Lyna Act Agreemet - 5AAn 4 787						
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QUALITY SYSTEM QUESTIONNAIRE

		ASSESSMENT QUESTIONS	Requirements	s	Number Ma or mi	N/A	N/E
8.2	2	Monitoring and measurement (continued)	•		• .		
8.2	2.1	Customer satisfaction MPR 1280	.8 6	ev	B		
03	orga	one of the measurements of the performance of the quality management system, does the nization monitor information relating to customer perception as to whether the organization met customer requirements (1)?		V		The state of the s	
04	Are t	the methods for obtaining and using this information determined?		./			
8.2	.2	Internal audit MPR 1280, C	es G				
	quali a) c	s the organization conduct internal audits at planned intervals to determine whether the try management system (2): conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization? and	M	1			
06	ls ar	n audit program planned, taking into consideration the status and importance of the esses and areas to be audited, as well as the results of previous audits?		√			
		e audit criteria, scope, frequency and methods defined?	•	\mathcal{L}			
		the selection of auditors and conduct of audits ensure objectivity and impartiality of the process (3)?		V			
		the organization ensure internal auditors do not audit their own work?		/			
	result	he responsibilities and requirements for planning and conducting audits, and for reporting ts and maintaining records (see 4.2.4) defined in a documented procedure?		\checkmark			
11	Do th	ne management responsible for the areas being audited ensure that actions are taken ut undue delay to eliminate detected nonconformities and their causes?	M	✓			
		ollow-up activities include the verification of the actions taken and the reporting of cation results (see 8.5.2) (4)?		√			
13	Are o	detailed tools and techniques developed such as check sheets, process flowcharts, by similar method to support audit of the quality management system requirements?		1			
14	Are t interi	the selected internal audit tools acceptable in measuring the effectiveness of the nal audit and overall organization performance?		/			***************************************
15	Do in	ternal audits also meet contract and/or regulatory requirements ?		7			
1) (2) I 3) (4) I	Give e Revie Check Revie	nce Notes examples of how customer's satisfaction is measured, committed, and acted upon. ew of audit plan (status of the previous year and progress of the current year). k the list of approved auditors. ew type of audits (questionnaire, synthesis, circulation, request for corrective actions, corrective	e`actions fo	llow-L	up).		
		e evidence assessed / Observations / Comments / N/A explanation		·~-111-d			
		st. Lat Save of frequens & Plojects - face to face Sampled 25 customer - reviewed results edit Schedul -	. Lileps	lan			***************************************
	••) Offic of Chief Counsel - LSO2200601 - Audit Rep	~				e
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S: Satisfactory - CAR: Corrective action required - Ma: Major corrective action - mi: Minor corrective action N/A: Not applicable - N/E: Not evaluated - P: Product - M: Management

NOR approve

QUALITY SYSTEM QUESTIONNAIRE		·			r .	
ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E	
8.2 Monitoring and measurement (continued)						_
8.2.3 Monitoring and measurement of processes	Key	E		·1	·	
16 Does the organization apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes?	-		NC			
17 Do these methods demonstrate the ability of the processes to achieve planned results?		/				
18 When planned results are not achieved, is correction and corrective action taken, as appropriate, to ensure conformity of the product?		/				
 19 In the event of process nonconformity, does the organization (1): a) take appropriate action to correct the nonconforming process? b) evaluate whether the process nonconformity has resulted in product nonconformity? 	P		Obo	***************************************		
and c) identify and control the nonconforming product in accordance with clause 8.3 ?	-	/				
8.2.4 Monitoring and measurement of product Q 0 - PA - 602	~ Chu	dl.	Propulse	- /	1mi	Lan a
20 Does the organization monitor and measure the characteristics of the product to verify that product requirements have been met?		1	100,000			4 77900
21 Is this carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1)?		/				
22 When key characteristics have been identified, are they monitored and controlled ?	Р	7				
23 When the organization uses sampling inspection as a means of product acceptance, is the plan statistically valid and appropriate for use ?		1				
24 Does the plan preclude the acceptance of lots whose samples have known nonconformities?		/				
25 When required, is the plan submitted for customer approval ?		1				
26 Is product held until it has been inspected or otherwise verified as conforming to specified requirements, except when product is released under positive-recall procedures pending completion of all required measurement and monitoring activities?	P					
27 Is evidence of conformity with the acceptance criteria maintained?		7				
28 Do records indicate the person(s) authorizing release of product (see 4.2.4)?						•
29 Is product release and service delivery held until all the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer ?		/				
Guidance Note						·
1) Give examples of non conformity (product, process,).						
Objective evidence assessed / Observations / Comments / N/A explanation		***************************************				
55 ME - Rosalyn Pathoch						
failure investigations, Mishap Reports - Ot	n: ad	20.	? 	- a	ch	ial Os
CSFR leview 5/3/06					***************************************	
HPOTP Blade Pled form. 471 + .079 Generic Dinemform	nagu				***************************************	
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S: Satisfactory - CAR: Corrective action required - Ma: Major corrective action - mi: Minor corrective action N/A: Not applicable - N/E: Not evaluated - P: Product - M: Management

Records OPR: Q010

QUALITY SYSTEM QUESTIONNAIRE	1				
ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
8.2 Monitoring and measurement (continued)					
8.2.4.1 Inspection documentation	- I	· · · · · · · · · · · · · · · · · · ·			
30 Are measurement requirements for product or service acceptance documented ?		1			
31 Does this documentation, which may be part of the production documentation, include : a) Criteria for acceptance and/or rejection ?	Р				
b) Where in the sequence measurement and testing operations are performed? c) a record of the measurement results? and		/			
 d) type of measurement instruments required and any specific instructions associated with their use? 					
32 Do test records show actual test results data when required by the specification or acceptance test plan?		/			
33 When required to demonstrate product qualification does the organization ensure that records provide evidence that the product meets the defined requirements?		/			
8.2.4.2 First article inspection	120000000000000000000000000000000000000			Limmon managi	brustua mar
34 Does the organization's system provide a process for the inspection, verification, and documentation of a representative item from the first production run of a new part, or	Р	-			
following any subsequent change that invalidates the previous first article inspection result (1) ?	111111111111111111111111111111111111111	/			
Guidance Note 1) Give examples of first article (new product and change). Objective evidence assessed / Observations / Comments / N/A explanation					
EV22-/EI-32 flyht Software E132 E132-6I-001. feer Review.					
MPLC leoject - Reer Reven April	132	-014	ip		***************************************
finding Log actions/actioner > 5CR					
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QUALITY SYSTEM QUESTIONNAIRE										
ASSESSMENT QUESTIONS	KEY Requirements	s	CAR Number Ma or mi	N/A	N/E					
3.3 Control of nonconforming product										
Note: The term "nonconforming product" includes nonconforming product returned from a	ustomer.									
Does the organization ensure that product which does not conform to requirements is identified and controlled to prevent its unintended use or delivery?	P	1								
36 Are the controls and related responsibilities and authorities for dealing with nonconforming product defined in a documented procedure?		V								
37 Does the organization's documented procedure define the responsibility for review and authority for the disposition of nonconforming product and the process for approving personnel making these decisions?		1								
88 Does the organization deal with nonconforming product in one or more of the following ways by: a) taking action to eliminate the detected nonconformity?	P			_						
 authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer? 					THE REPORT OF THE PARTY.					
c) taking action to preclude its original intended use or application?										

Objective evidence assessed / Observations / Comments / N/A explanation

the nonconformity results in a departure from the contract requirements?

(Unless otherwise restricted in the contract, is organization-designed product, which is controlled via a customer specification, dispositioned by the organization as-use-as is or repair, provided the nonconformity does not result in a departure from customer-

40 Is product dispositioned for scrap conspicuously and permanently marked, or positively

41 Are records of the nature of nonconformities and any subsequent actions taken, including

42 When nonconforming product is corrected, is it subject to re-verification to demonstrate

43 When nonconforming product is detected after delivery or use has started, does the organization

44 In addition to any contract or regulatory authority reporting requirements, does the organization's system provide for timely reporting of delivered nonconforming product

45 Does notification include a clear description of the nonconformity, which includes as necessary, parts affected, customer and/or organization part numbers, quantity, and

take action appropriate to the effects, or potential effects, of the nonconformity ?

authorized by the customer, if

specified requirements ?)

conformity to the requirements?

date(s) delivered?

that may affect reliability or safety ?

the product is produced to customer design? or

controlled, until physically rendered unusable?

concessions obtained, maintained (see 4.2.4)?

5'CLR# 1084 SRB Approval-SRB Membership Memor - approval of Membership SRB Neview board Chester -

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		QUALITY SYSTEM QUESTIONNAIRE	1 1000	_		T	1
		ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
8.4	ţ	Analysis of data					
46	suita	s the organization determine, collect and analyse appropriate data to demonstrate the ability and effectiveness of the quality management system and to evaluate where continual covernent of the effectiveness of the quality management system can be made?	M	/		THE THE PROPERTY OF THE PARTY O	
47		s this include data generated as a result of monitoring and measurement and from other vant sources?	The state of the s	/			
	a) b) c)	s the analysis of data provide information relating to : customer satisfaction (see 8.2.1) (1) ? conformity to product requirements (see 7.2.1) ? characteristics and trends of processes and products including opportunities for preventive action ? And		/	-		THE WASTER THE
	d)	suppliers?					
		examples and check how the organization measures the effectiveness.					
Obj	ecti	ve evidence assessed / Observations / Comments / N/A explanation					
P		Onbital Meling Plan - Per E 132-049 - hoj. Summay Shed - charge Request Progress Mobiles - SCR Assering - SW Size Medicies Orbital Stoffeny Medicie Volafitety Melicie SW Rev. Improvent Melicie SPF Change Regard CM MI Medicie M. I Ding of thick					
	U	Management Review activity					

		QUALITY SYSTEM QUESTIONNAIRE					
		ASSESSMENT QUESTIONS	KEY Requirements	S	CAR Number Ma or mi	N/A	N/E
8.	5	Improvement					
8.	5.1	Continual improvement					
49	throu	s the organization continually improve the effectiveness of the quality management system ugh the use of the quality policy, quality objectives, audit results, analysis of data, corrective preventive actions and management review?		√			
8.	5.2	Corrective action MPR 1/2-80, 4					
50		s the organization take action to eliminate the cause of nonconformities in order to prevent rrence (1)?	P				
51	Are (Corrective actions appropriate to the effects of the nonconformities encountered?		/			
8.8	a) r b) c c) e d) c e) r f) r g) f t h) s	documented procedure established to define requirements for : reviewing nonconformities (including customer complaints)? determining the causes of nonconformities? evaluating the need for action to ensure that nonconformities do not recur? determining and implementing action needed? recording of the results of the action taken (see 4.2.4)? reviewing corrective action taken? Flow down of the corrective action requirement to a supplier, when it is determined that the supplier is responsible for the root cause? and specific actions where timely and/or effective corrective actions are not achieved? Preventive action It the organization determine action to eliminate the causes of potential nonconformities in	M				
•		to prevent their occurrence (2)? Afects #2820		1			
55 Gu	ls a d a) d b) e c) d d) n e) re	documented procedure established to define requirements for: documented procedure established to define requirements for: determining potential nonconformities and their causes? determining the need for action to prevent occurrence of nonconformities? determining and implementing action needed? decording of the results of the action taken (see 4.2.4)? and deviewing preventive action taken?	rned/l	Best	Pracj	ties	
1) 2)	Selec	ct a non-conforming part and use 52 a) through h) to check for effectiveness. ct a non-conforming part and use 55 a) through e) to check for effectiveness.					
Obj	ectiv	ve evidence assessed / Observations / Comments / N/A explanation			······································	····	
€	,	to Better Utiliza om facilitée - Team of le - fr. Jim C improvement in estilipation	Carte				
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		SDN + 175 > 12cAn + 242 - S: Satisfactory - CAR: Corrective action required - Ma: Major corrective action - mi: N/A: Not applicable - N/E: Not evaluated - P: Product - M: Manager	Minor correc		7		
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Annex A (informative)

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